MERIDIAN
MEDICAL TECHNOLOGIES
A Pfizer Company

Meridian Medical Technologies®, Inc.
1945 Craig Road
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June 28, 2018

Miguel A. Hernández
Director, Compliance Branch
US Food and Drug Administration
8050 Marshall Drive, Suite 205
Lenexa, KS 66214

RE: Meridian Medical Technologies, Inc. / FEI Number: 1950222
(b) (4) Enhancement Plan
March 01, 2018 – May 31, 2018 Update

Dear Mr. Hernández:

In the December 17, 2014 response to the Form FDA 483 issued November 25, 2014, Meridian Medical Technologies, Inc. ("MMT") included a commitment to provide FDA with a comprehensive description of actions being taken to enhance the capability of the (b) (4) and (b) (4) filling equipment prior to resuming production of auto-injectors (the "(b) (4) Enhancement Plan" or "Plan"). As reported out in the previous quarterly report, MMT decided to replace the (b) (4) filler with new contemporary filling equipment.

The "Plan" was submitted on February 28, 2015. MMT also committed to submitting quarterly updates, the first of which was provided on June 12, 2015. MMT hereby provides the thirteenth quarterly update to cover the time period from March 01, 2018 – May 31, 2018.

In addition, in MMT's April 14, 2017 Response to FDA Form 483 issued March 24, 2017, MMT committed to complete the revalidation of the ATNAA/DuoDote processes end to end as an action item to address observation 13B of the 483. The revalidation was communicated to be completed by June 29, 2018 in this response. Due to an Out Of Limit result of a bulk release bioburden test for a Process Validation (PV) lot formulated in March 2018, an investigation was initiated to determine root cause and identify corrective actions. The API lot was implicated by the investigation and the respective product formulated from this API lot was rejected. Identified corrective actions were implemented prior to the PV being restarted in April 2018. Currently, MMT is in-process of completing the process validation activities. MMT will not complete the

validation activities by June 29, 2018 due to delayed restart and two investigations that are open, which have resulted in a hold to determine root cause and any necessary corrective actions prior to proceeding to final packaging on two validation lots. We will update FDA on the status of the process validation in the 2Q2018 FDA 483/Warning Letter Quarterly Update, which will be submitted to the FDA Kansas City District Office and FDA CDER Office of Manufacturing Quality by July 31, 2018.

The information related to the ATNAA/DuoDote PVs is being included for information purposes and the enclosed update to the "Plan" will remain focused on updates to actions being taken to enhance the capability of the filling equipment prior to resuming production of auto-injectors originally filled on the (b) (4) and (b) (4).

Background

Following an FDA inspection that concluded in April 2013, MMT committed to implementing corrective actions for the production of products that relied exclusively on manual visual inspection for the detection of missing drug. This commitment applied to products manufactured on the (b) (4) filler and also for products manufactured on the (b) (4) filling line, which used manual visual inspection for detection of missing drug. MMT also identified opportunities to enhance the process for products produced on the (b) (4) filling line, which used a (b) (4) and manual visual inspection to detect missing drug.

As previously reported, MMT's focus had been on ATNAA/DuoDote manufacturing process enhancements using the (b) (4) filler, which was directed by MMT's key client. In May 2015, MMT received direction from its client to resume work on the (b) (4) enhancement activities after the aseptic site maintenance spring shutdown concluded. (b) (4) (b) (4) (b) (4)

As outlined in previous quarterly reports, MMT decided to procure a new (b) (4) filler replacing the legacy (b) (4) filler. The new (b) (4) filler was designed to meet contemporary manufacturing standards such as (b) (4) that could not be implemented on the (b) (4) filler.

As previously reported, process qualification and product validation in support of the (b) (4) NDA submission will be conducted on the new (b) (4) filler using glass cartridges from a new supplier (b) (4) that in initial studies showed improved qualities over the original glass cartridges.

The current timeline covering the procurement and qualification activities that are in progress for the new (b) (4) filler is provided as **Exhibit 1**.

New (b) (4) filler Plan Update

Following MMT's decision to pursue the process qualification and product validation in support of the submission of the (b) (4) NDA on the new (b) (4) filler, the supplier (b) (4) finalized the initial fabrication of the new filler (b) (4) filler') and Factory Acceptance Testing was successfully completed in December 2017. The filler was delivered onsite in January 2018 and Site Acceptance Testing (SAT) was successfully completed in March.

The aseptic suite to house the new (b) (4) Filler was re-integrated into the aseptic core during the regular 2018 spring shutdown of the aseptic processing area and Installation and Operations Qualification of the (b) (4) filler was successfully completed.

MMT is currently in the process of conducting capability and defect baseline studies. Updates on these activities will be provided in future quarterly updates.

Projected milestones for the procurement and qualification actions for (b) (4) on the new (b) (4) filler in progress, based on input from MMT's customer, product priorities, and access to the aseptic core are provided as **Exhibit 1**. This timeline may require further adjustment based on additional findings and necessary corrective actions.

In consultation and alignment with MMT's clients, the activities for (b) (4) have been put on hold until qualification, NDA submission and approval of (b) (4) is complete.

AtroPen-style auto-injector Enhancement Plan Update

As reported in previous quarterly updates for the AtroPen-style auto-injector products that were produced on the (b) (4) MMT has identified (b) (4) as an alternate material to the current (b) (4) material used for the AtroPen-style cartridge. The alternate material is intended to address (b) (4) issues that have been observed in the AtroPen and Morphine auto-injectors during stability.

After the initial trials that used an (b) (4) were not successful, MMT continues to work with the (b) (4) (b) (4)

(b) (4)

(b) (4)

Updates on these activities will be provided in future quarterly reports.

The updated timeline that also takes into consideration input from MMT's customer, product priorities, anticipated timing for procurement of a new filler for AtroPen-style cartridges and access to aseptic core is provided as **Exhibit 2** outlining the projected milestone dates. This timeline may require further adjustment based on additional findings and necessary corrective actions.

MMT's next quarterly update on the Plan will be submitted by September 30, 2018 (for the three month period ending August 31, 2018). In the interim, please feel free to contact me with any questions or input.

Sincerely,

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